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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/737,251	12/15/2003	Pal Maliga	1594-RUT.03-083US	6673

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EXAMINER

KUBELIK, ANNE R

ART UNIT PAPER NUMBER

1638

DATE MAILED: 03/30/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/737,251

Applicant(s)

MALIGA ET AL.

Examiner

Anne R. Kubelik

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 03 February 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) 1-6 and 11-17 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) 7-10 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### DETAILED ACTION

1. Applicant's election with traverse of Group 28 (claims 7-10) in the reply filed on 3 February 2006 is acknowledged. The traversal is on the ground(s) that SEQ ID NOs: 4-30 are derivatives of a PrnP1 promoter and differ in a linear fashion from one another by three bases; because of the very high similarity and homology of the sequences a search of one sequence should encompass all of the sequences. This is not found persuasive because a search on one sequence will not necessarily find all the art on all the other sequences; thus, each sequence requires an independent search of the databases. It is also noted that Applicant did not state that the sequences were not patentably distinct over each other.

Applicant did not argue the restriction between the elected Group and any of the other Groups.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-6 and 11-17 are withdrawn from consideration as being drawn to nonelected inventions.

2. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825.

The Brief Description of Fig. 5A says that portions of SEQ ID NOs:3, 21, 22 and 37 are presented. This should be amended to either recite which base number of those SEQ ID NOs: are presented or to give the sequences shown their own sequence identifiers.

The Brief Description of Fig. 8 lists two sequence identifiers, but the figure shows three different sequences. A sequence identifier is missing; as the first sequence and the second sequence are different lengths, they cannot both be SEQ ID NO:3.

Full compliance with the sequence rules is required in response to this Office action. A complete response to this Office action must include both compliance with the sequence rules and a response to the issues set forth herein. Failure to fully comply with both of these requirements in the time period set forth in this Office action will be held to be non-responsive.

3. The disclosure is objected to because it is not clear what Appendix I is. It appears to be a variation of some of the Figures presented in the drawings, and is thus repetitive and confusing.

#### ***Claim Rejections - 35 USC § 112***

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 7-10 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contain subject matter that was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims are broadly drawn to a promoter comprising mutations in the operon SEQ ID NO:51, wherein the mutations minimize homologous recombination with SEQ ID NO:51, constructs comprising the promoter, vectors comprising the constructs, and plants comprising the vector.

The instant specification, however, only provides guidance for methods of assaying plastid promoter function (example 1), analysis of mutants of the tobacco Prn promoter to identify the promoter elements (example 1) and a promoter, SEQ ID NO:51, that has neutral mutations in it relative to the wild-type Prn.

The instant specification fails to provide guidance for promoters comprising mutations in the operon SEQ ID NO:51, wherein the mutations minimize homologous recombination with SEQ ID NO:51.

First, SEQ ID NO:51 is not an operon; the specification even states that it is a Prn promoter derivative (pg 30, lines 30-32). Second, the specification fails to teach any plant comprising SEQ ID NO:51.

Assaying mutations in SEQ ID NO:51 that would minimize homologous recombination with SEQ ID NO:51 would not only require assaying for promoter function, but would also require *in vivo* assaying for minimization of homologous recombination upon transformation into plastids. The specification states that “[I]n vivo promoter analysis is very labor intensive” (pg 21, line 25). Thus, such assays would require undue experimentation.

As the specification does not describe the transformation of any plant with promoters comprising mutations in the operon SEQ ID NO:51, undue trial and error experimentation would be required to screen through the myriad of nucleic acids encompassed by the claims and plants transformed therewith, to identify those, wherein homologous recombination with SEQ ID NO:51 is minimized, if such plants are even obtainable.

Given the claim breath, unpredictability in the art, and lack of guidance in the specification as discussed above, the instant invention is not enabled.

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6. Claims 7-10 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The essential feature of the claims are promoters comprising mutations in the operon SEQ ID NO:51, wherein the mutations minimize homologous recombination with SEQ ID NO:51. The specification describes structures responsible for Prn promoter function, but does not describe any structures that minimize homologous recombination with SEQ ID NO:51. No promoters comprising mutations in the operon SEQ ID NO:51, wherein the mutations minimize homologous recombination with SEQ ID NO:51 are disclosed or reduced to practice. Since the disclosure fails to describe the common attributes that identify members of the genus, and because the genus is highly variant, the specification fails to provide an adequate written description of the claimed invention.

Therefore, given the lack of written description in the specification with regard to the structural and functional characteristics of the claimed compositions, it is not clear that Applicant was in possession of the claimed genus at the time this application was filed.

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 7-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that Applicant regards as the invention. Dependent claims are included in all rejections.

Claim 7 lacks antecedent basis for the limitation "the Prm operon" in line 3.

***Claim Rejections - 35 USC § 102***

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 7-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Maliga et al (1999, US Patent 5,877,402).

Maliga et al teach a promoter comprising mutations that would minimize homologous recombination with SEQ ID NO:51, constructs comprising the promoter, vectors comprising the constructs, and plants comprising the vector (example 2).

***Conclusion***

11. No claim is allowed.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne R. Kubelik, whose telephone number is (571) 272-0801. The examiner can normally be reached Monday through Friday, 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg, can be reached at (571) 272-0975.

The central fax number for official correspondence is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of

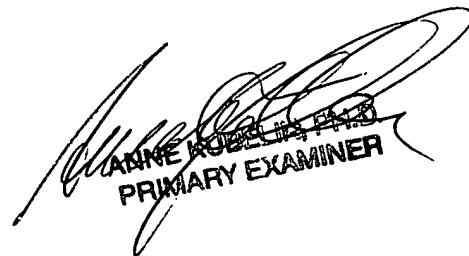
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For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Anne Kubelik, Ph.D.

March 27, 2006



ANNE KUBELIK, PH.D.  
PRIMARY EXAMINER